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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,827	09/07/2004	Janusz B. Pawliszyn	PAT 804W-2	8910

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,827	PAWLISZYN, JANUSZ B.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *101-107,109,118 and 119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *101-107,109,118 and 119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1 – 100, 108, and 110 – 117 have been cancelled.

Currently, claims 101 – 107, 109, 118 and 119 are pending.

Withdrawn Rejections

All previous rejections of the claims have been withdrawn in light of Applicant's amendments and arguments filed August 16, 2006.

Response to Arguments

Applicant's arguments, see p6-8, filed August 16, 2006, with respect to the rejection(s) of claim(s) 101 under 35 U.S.C. 102 as being anticipated by Pompidou et al. (US 6,689,603) have been fully considered and are persuasive with respect to the added limitation requiring the fibre to be a "flexible wire." The amendment to claim 101 wherein the "fibre is a flexible wire" is not taught or anticipated by the cited prior art reference of Pompidou et al. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Faxon et al. (US 5,464,395).

Pompidou et al. teach a device for in situ analysis of a substrate, wherein the substrate includes an animal or animal tissue, said device comprising:

at least one microsystem 2 (fibre) having a coated end which is at least partially coated with specific antibodies 4 (an extraction phase) for binding (extracting) an antigen (component) present in the substrate; and

a flexible rod 1 (positioning device) for guiding said coated end into position within the animal or animal tissue, said flexible rod comprising:

a deformable catheter for placement within an animal or animal tissue through which said microsystem extends, said catheter having an open end for positioning within said animal or animal tissue and said catheter being immobilized during sampling with respect to the animal or animal tissue; and

a rigid support 3 (fibre holding region) attached to said microsystem, said support being movable with respect to the catheter, to move said coated end of the microsystem into or out of the animal or animal tissue (see Figures 1, and 3-5; and column 1, lines 8-12 and lines 35-65; column 2, lines 2-56; column 3, lines 6-10 and lines 43-59; column 4, lines 4-19 and lines 49-64; column 5, lines 5-19 and lines 52-54; column 6, lines 13-17; and column 8, lines 58-67).

However, Pompidou et al. fail to teach that the microsystem (fibre) is a flexible wire.

Faxon et al. teach a catheter device for delivering therapeutic and/or diagnostic agents directly into the tissue surrounding a bodily passageway. The catheter 5 comprises an elongated body 10 and a means 15 for directing the catheter through one or more bodily passageways to a desired site. The means 15 for directing the catheter comprises a central passageway 40 that is adapted to slidably accommodate a guidewire 45 extending therethrough. The guidewire 45 is typically formed out of a strong flexible wire such that it can be passed through various bodily passageways to reach a remote site within a patient's body (see Figures 1 and 2; Abstract; and column 5, lines 21-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microsystem and rigid support of Pompidou et al. to comprise a flexible wire as taught by Faxon et al. because Faxon et al. teach the benefit of using a guidewire and catheter for in-vivo applications, wherein the

guidewire is formed out of a strong flexible such that it can be passed through various bodily passageways in order to reach a remote site within a patient's body.

Claims 102, 103, 106, 109 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Faxon et al. (US 5,464,395), as applied to claim 101, and further in view of Gourley et al. (US 5,120,510).

The Pompidou et al. reference, which was discussed above, teaches that the device is biocompatible, but fails to teach that the microsystem (fibre) is coated with a biocompatible protection layer, such as polypyrrole or derivatized cellulose. Pompidou et al. further fail to teach that the extraction phase, i.e. specific antibodies, contain a fluorescent label or enzyme, or that the microsystem (fibre) comprises a plurality of microsystems. The Faxon et al. reference further fails to teach these missing limitations.

Gourley et al. teach a sensor device comprising an optical fiber for use in sensing the concentration of a component in a medium. The optical fiber 12 contains a sensing element 18, which comprises a coating of a polymeric matrix. The polymeric matrix, which preferably comprises dimethylsiloxane polymers, allows for permeability of the component the concentration of which is to be determined or measured by the sensor system. The fiber and sensing element further contain an overcoating 20, which preferably comprises a cellulosic material (derivatized cellulose). The sensor system is created in order to allow for it to be suitable for use in vivo in a human patient. Additionally, the fiber and sensing element utilizes an optical indicator, preferably a

fluorescent dye, which is sensitive to the component of interest and allows for determination of the concentration of the component. Further, the system utilizes one or more optical fibers, which allows for measuring a plurality of different components of interest (see Figure 1; and column 2, lines 60-65; column 3, lines 62-68; column 4, lines 1-60; column 6, lines 39-55; column 7, lines 34-58; and column 9, lines 5-68).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. and Faxon et al. the coating with a biocompatible layer and also the use of polymeric matrix coating as an extraction phase as taught by Gourley et al. because Gourley et al. teach the benefit of the coatings of a sensor system with a cellulosic material and a polymeric matrix coating, because they allow for permeability of the component of interest to be measured and allow for the sensor to be suitable for use in vivo in a human patient. It also would have been obvious to use a fluorescent indicator with the extraction phase as taught by Gourley et al. because the indicator is sensitive to the component of interest and allows for determination of the concentration of the component. Further, it would have been obvious to use multiple fibers as taught by Gourley et al. because multiple fibers allows for measuring a plurality of different components of interest.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Faxon et al. (US 5,464,395), as applied to claim 101 above, and further in view of Colburn et al. (US 2003/0183758).

The device of Pompidou et al. meets the structural limitations of both the fiber and extraction phase, therefore, enabling the device to be useful in a variety of analytical instruments, however, Pompidou et al., as well as Faxon et al., fail to teach the use of MALDI-TOFMS analysis specifically.

Colburn et al. teach that matrix-assisted laser desorption/ionization (MALDI) in combination with time-of-flight (TOF) analyzers have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers (see paragraph 0003, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the MALDI-TOFMS combination as taught by Colburn et al. as the analytical instrument for the device of Pompidou et al. and Faxon et al. because Colburn et al. teach the benefit of using MALDI-TOF analyzers because they have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Faxon et al. (US 5,464,395), as applied to claim 101 above, and further in view of Riviere et al. (US 2003/0180954).

Pompidou et al. and Faxon et al. further fail to teach the addition of a calibrant to the extraction phase of the fiber.

Riviere et al. teach the use of polydimethylsiloxane coated fibers as skin-imitating membranes in order to study permeation of chemicals into these membranes (see paragraph 0037). The absorption parameters, referred to as molecular descriptors, of each chemical compound is obtained by comparing to its calibration standard, wherein the standards were created by analyzing fifty compounds and their subsequent molecular descriptors (see paragraphs 0167-0169). The calibration standards determine the system constants, which reflect the properties of the membrane (fibers) and will not change with different solutes, therefore, the molecular descriptors of unknown/study compounds can be obtained (see paragraph 0170).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the extraction phase of the microsystem of Pompidou et al. and Faxon et al. a calibration standard (calibrant) as taught by Riviere et al. because Riviere et al. teach the benefit of using calibration standards to determine the system constants because they reflect the properties of the fibers, which will not change and thus enable the absorbance of unknown compounds to be studied.

Claims 107 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Faxon et al. (US 5,464,395), as applied to claim 101 above, and further in view of Pawliszyn (US 5,691,206).

Pompidou et al. and Faxon et al. fail to teach that the device comprises an openable housing for said microsystem (fiber), wherein said housing can comprise a needle.

Pawliszyn teaches a device for solid phase microextraction comprising a fiber 6, which contains a coating selective for a component of interest (extraction phase), and a metal sleeve 24 and hollow needle 18, which houses the fiber. The purpose of the housing of the fiber by the metal sleeve and hollow needle is to protect the fiber from damage when not in use. Further, the device is enabled for solid phase microextraction in both in-vivo and in-vitro samples (see Figures 1 and 2; and column 2, lines 10-21; column 3, lines 5-16; and column 5, lines 10-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. and Faxon et al. an openable housing comprising a needle for housing the microsystem (fibre) as taught by Pawliszyn because Pawliszyn teach the benefit of housing a fiber for use in in-vitro or in-vivo sampling for extraction purposes in order to protect the fiber from damage when not in use.

Response to Arguments

Applicant's arguments filed August 16, 2006 with respect to the Pompidou et al. reference not teaching a "solid phase microextraction device" (see p6-8) were not considered persuasive. The device of Pompidou et al. contains all of the required limitations of the instant application's device, except for the added limitation requiring the fibre to be a "flexible wire." This deficiency was remedied above, with respect to the Faxon et al. reference, and therefore, the only argument remaining is over the intended use of the device. The Pompidou et al. device utilizes antibodies as the "extraction

phase" for binding to desired components of interest (see Figures; and column 2, lines 16-25). The instant application does not recite a specific compound or coating for the "extraction phase," and even allows for the extraction phase to include an immobilized antibody (claim 103), as taught by the Pompidou et al. reference. Therefore, the recitation for the device to comprise a "solid phase microextraction device" represents the intended use of the device, and because the device of Pompidou et al. contains all of the required components, including the flexible wire, in view of Faxon et al., the device is capable of performing solid phase microextraction.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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